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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/715,797

11/18/2003

Steve Golden

CSI-2009C1

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EXAMINER

WOO, JULIAN W

ART UNIT

PAPER NUMBER

3773

MAIL DATE

DELIVERY MODE

05/21/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/715,797	<b>Applicant(s)</b> GOLDEN ET AL.	
	<b>Examiner</b> Julian W. Woo	<b>Art Unit</b> 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 April 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 64,66-81 and 123-141 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 76-81 is/are allowed.
- 6) ☒ Claim(s) 64,66-75,123-132,135-137 and 139-141 is/are rejected.
- 7) ☒ Claim(s) 133, 134, and 138 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/5/08</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

1. The finality of the Office action of November 14, 2007 is hereby withdrawn.

#### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 64, 123, 124, 125, and 127-131 are rejected under 35 U.S.C. 102(e) as being anticipated by LaFontaine et al. (6,443,158). LaFontaine et al. disclose, at least in figures 3, 5A-6E and 14A and col. 3, line 66 to col. 6, line 14; col. 7, lines 27-61; and col. 11, lines 56-67; a method for performing anastomosis, where method includes delivering a tubular member (58) or cannula into the interior of a vessel (16) having a vessel wall, passing or introducing the first end of the tubular member or cannula from the interior through the vessel wall at a first vessel wall location, attaching a graft (86 or 214 and 216) to the vessel wall adjacent to the first end of the tubular member or cannula, and removing the tubular member or cannula, where the tubular member or cannula is passed through the vessel wall at a second location (e.g., in a femoral artery) to deliver the first end of the tubular member or cannula into

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the interior of the vessel, where the tubular member or cannula is delivered endovascularly, and where the tubular member or cannula forms an area of hemostasis (at contact with sides of the incisions).

4. Claims 66-74, 126, 132, 135-137, and 139-141 are rejected under 35 U.S.C. 102(e) as being anticipated by LeMole (5,893,369). LeMole discloses, at least in figures 5-9A and 12A-13 and in col. 1, line 59 to col. 2, line 2 and col. 5, line 34 to col. 8, line 35; a method for performing an anastomosis on a vessel wall while maintaining blood flow within the vessel (12), where the method includes forming an opening in the blood vessel (see figs. 6 and 7 or 12E) and removing a portion of the wall where the opening was formed (see fig. 8 or 12F), inserting an occluding member into the opening (38 or 302), anastomosing a graft (14) to the vessel, piercing the vessel wall with an anchor member (34 or 306), cutting the opening around the anchor member with a cutting tool (32 or proximal portion of 302), removing a tissue plug produced by the cutting prior to inserting an occluding member (see fig. 8 or 13F), inserting the occluding member (302) into the opening cut into the vessel while the cutting tool is still in the opening, withdrawing the cutting tool to allow the occluding member to expand against the periphery of the opening, placing a graft (14) over the occluding member prior to anastomosing, sliding a generally circular centering disk (30) along the anchor member onto the vessel wall prior to cutting and clamping vessel wall tissue between the centering disk and an end portion of the anchoring member, removing the clamped vessel wall between the centering disk and a portion of the piercing member, where anastomosing comprises

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fastening walls of the graft and vessel together using fasteners (24), where the occluding member comprises a cannula (304), where the occluding member (302) is radially expandable or inflatable and has an expandable membrane or flexible sealing member, where the occluding member forms an umbrella (see fig. 12C), and where the method includes a restraining sheath (30E).

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claim 75 is rejected under 35 U.S.C. 103(a) as being unpatentable over LeMole (5,893,369) in view of Ho et al. (6,514,265). LeMole (5,893,369) discloses the invention substantially as claimed, but do not disclose fastening with self-closing fasteners. Ho et al. teach, at least in figures 2A –3G and in col. 5, line 62 to col. 6, line 13 and col. 8, lines 9-42, fastening the walls of a graft and a vessel together using self-closing fasteners (210). It would have been obvious

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to one having ordinary skill in the art at the time the invention was made, in view of Ho et al., to modify the method of LeMole, so that self-closing fasteners are applied for the fastening of a graft to a vessel. Such fasteners would allow a quick (as compared to the time for fastening with sutures or conventional clips), safe, and effective anastomosis of a graft and a vessel within the narrow confines of a surgical site.

***Allowable Subject Matter***

7. Claims 76-81 are allowed.
8. The following is an examiner's statement of reasons for allowance: None of the prior art of record, alone or in combination, discloses, a method from performing an anastomosis on a vessel wall, where the method includes, inter alia, inserting an occluding member into an opening cut into a vessel, and anastomosing a graft to the vessel at the opening, where the occluding member includes fasteners with attached needles attached to the occluding member, where the method further includes grasping the needles and pulling them entirely through the vessel wall; and where a cutting tool includes an adapter that retains needles, where the method includes inserting the cutting tool and adapter into the vessel and pulling back the adapter and cutting tool in order to pierce the vessel wall with the needles, and pulling the needles all the way through the vessel.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should

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preferably accompany the issue fee. Such submissions should be clearly labeled

“Comments on Statement of Reasons for Allowance.”

9. Claims 133, 134, and 138 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination, discloses a method for performing an anastomosis on a vessel wall while maintaining blood flow within the vessel, where the method includes, inter alia; forming an opening in a wall of the vessel and inserting an occluding member into the opening, where the occluding member is radially expandable and comprises a plurality of wires of memory shape, and where the occluding member comprises a plurality of expansion members and a membrane between expansion members.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

### ***Response to Amendment***

11. Applicant's arguments filed on March 7, 2008 have been fully considered but they are not fully persuasive: See the new and restated grounds of rejection above.

The arguments regarding the rejection of claims based on the reference of Swanson et al. are moot in view of new grounds of rejection, which are made without prejudice regarding the rejection based on Swanson et al. That is,

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Swanson et al. indeed disclose a cannula (110). Element 110 is an elongated, tubular element that includes a lumen, so it defines a cannula. Moreover, the rejection of November 14, 2007 was properly made final, because the Applicant had amended the claims, which necessitated changes to the rejection based on Swanson et al.

With respect to arguments regarding the rejection of claims based on the Lemole reference: LeMole indeed discloses forming an opening in the vessel wall before and during anastomosing a graft to the vessel at the opening. That is, forming the opening completes the anastomosing process by forming a flow path between the graft and the vessel. In other words, the graft is connected, i.e., anastomosed, to the vessel without and with an opening formed. Also, blood flow within the vessel is indeed maintained during the method. As suggested in col. 1, 59 to col. 2, line 2; the method of LeMole is performed *in contrast* to “conventional heart bypass surgery,” where there is “stoppage of blood flow.”

### ***Conclusion***

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Julian W. Woo/  
Primary Examiner, Art Unit 3773

May 20, 2008